UNITED STATES DISTRICT COURT
DISTRICT OF NEBRASKA

UNITED STATES OF AMERICA,

Plaintiff,

v.

NOVA-TECH, INC., a corporation, and GLORIA J. THESENVITZ, an individual,

Defendants.

Civil Case No. 8:07-cv-257-RGK-DLP

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for permanent injunctive relief against Nova-Tech, Inc. ("Nova-Tech"), a corporation, and Gloria J. Thesenvitz, an individual (collectively, "Defendants"), and Defendants having appeared and having consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act").

3. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of

21 U.S.C. § 351(a)(2)(B), in that they have been manufactured, processed, packed, labeled, and held in violation of current good manufacturing practice ("CGMP"). See 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. Parts 210 and 211.

4. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of articles of drug, as defined by 21 U.S.C. § 321(g)(1), after shipment of one or more of their components in interstate commerce.

5. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any articles of drug unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in compliance with CGMP. See 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. Parts 210 and 211;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "expert"), to make inspections of their drug manufacturing facilities to determine whether their methods, facilities, and controls are operated and administered in conformity with CGMP. The expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families. Defendants shall notify FDA in writing of the identity of the expert as soon as they retain such expert;

C. The expert performs a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, pack, label, hold, and distribute drugs to determine whether they are in compliance with CGMP;

D. The expert certifies in writing to FDA that: (1) he or she has inspected Defendants' facilities, methods, processes, and controls; (2) all CGMP deviations brought to Defendants' attention by FDA since December 1999, or by the expert, or through any other source have been corrected; and (3) such facilities, methods, processes, and controls are in compliance with CGMP. As part of this certification, the expert shall include a full and complete written report with the detailed results of his or her inspection;

E. Defendants report to FDA in writing the actions they have taken to: (1) correct the CGMP deviations brought to Defendants' attention by FDA, the expert, and any other source; and (2) ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP;

F. FDA representatives inspect Defendants' facilities to determine whether the requirements of this Decree have been met, and whether Defendants are operating their facilities in conformity with the Act, its implementing regulations, and this Decree; and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 5(A)-(E).

6. After Defendants receive written notice from FDA pursuant to Paragraph 5(G) that they appear to be in compliance with Paragraphs 5(A)-(E) of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors,

and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, any article of drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

B. Violates 21 U.S.C. § 331(k) by causing any article of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), after shipment of one or more of its components in interstate commerce.

7. After Defendants have complied with Paragraphs 5(A)-(E) and FDA has notified them pursuant to Paragraph 5(G), Defendants shall retain an independent person or persons (the "auditor") to conduct audit inspections of their drug manufacturing operations not less than once every six (6) months for a period of five (5) years. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families. If Defendants choose, the auditor may be the same person or persons retained as the expert in Paragraph 5(B).

A. At the conclusion of each audit inspection, the auditor shall prepare a written audit report (the "audit report") analyzing whether Defendants are in compliance with CGMP and identifying any deviations from CGMP ("audit report observations"). As a part of

every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten (10) business days after the date the audit inspections are completed. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any audit report observations indicating that Defendants are not in compliance with CGMP, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

8. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data prepared or submitted by Defendants, the expert, the auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to immediately take appropriate action, including, but not limited to, one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, and distributing any or all drug(s);

B. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

C. Submit additional reports or information to FDA;

D. Recall specified drug products released or distributed by Defendants or that are under the custody and control of Defendants' agents, distributors, customers, or consumers. Defendants shall bear the costs of such recall(s); and

E. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with the Act, its implementing regulations, or this Decree.

9. Upon receipt of any order issued by FDA pursuant to Paragraph 8, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 8 shall continue until Defendants receive written notification

from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Decree, and that Defendants may, therefore, resume operations.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' place(s) of business and without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any and all drug products, including components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

11. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Decree or that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $78.09 per hour and fraction thereof per representative for inspection work; $93.61 per hour or fraction thereof per representative for analytical or review work; $0.485 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published

government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

12. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or registered mail, to each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, and post for a minimum of thirty (30) calendar days, a copy of this Decree in the employee common areas of their manufacturing facility. Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons who have received a copy of this Decree.

13. Defendants shall notify FDA at least fifteen (15) calendar days before any change in ownership or character of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure of Nova-Tech, Inc., or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any potential successor or assign at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

14. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the Director, FDA Kansas City District Office, 11630 West 80th Street, Lenexa, Kansas 66214.

15. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such action.

16. Defendants shall abide by the decisions of FDA, which decisions shall be final. FDA decisions under this Decree shall be reviewed by the Court, if contested, under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

17. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

Dated this 25th day of September, 2007.

IT IS SO ORDERED:

HON. RICHARD G. KOPF
UNITED STATES DISTRICT JUDGE

Entry consented to:

FOR DEFENDANTS:

GLORIA I. THESENVITZ,
Individually, and on behalf of Nova-Tech, Inc. as its President

JAMES S. MITCHELL, Esq.
Attorney for Defendants
Bar No. 12863
1005 South 107th Avenue, Suite 101
Omaha, NE 68114
Telephone: (402) 493-3300
Fax: (402) 496-0766
Email: lawman000@aol.com

FOR PLAINTIFF:

JOE W. STECHER
United States Attorney

ALAN J. PHELPS
D.C. Bar No. 475938
Trial Attorney
Office of Consumer Litigation
Department of Justice
Civil Division
P.O. Box 386
Washington, DC 20044
Telephone: (202) 307-6154
Fax: (202) 514-8742
Email: alan.phelps@usdoj.gov